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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/725,508

12/03/2003

Akio Kawamura

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03/27/2008

GRIFFIN & SZIPL, PC

SUITE PH-1

2300 NINTH STREET, SOUTH

ARLINGTON, VA 22204

EXAMINER

CHAPMAN, GINGER T

ART UNIT

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3761

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/725,508	Applicant(s) KAWAMURA, AKIO	
	Examiner Ginger T. Chapman	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,7,8,10,11 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,7,8,10,11 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

Claims 2, 4-6, 9 and 12 are cancelled. Claims 1, 3, 7-8, 10-11 and 13 are pending in the application.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 7-8, 10-11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawamura (US 6,231,541 B1).

3. With regard to claims 1 and 13, Kawamura discloses a no-needle blood access device for hemodialysis comprising an elongated metallic body (c. 7, ll. 42) provided at its upper surface with a recess (38, 40) being formed with a peripheral wall (24) defining a well (26) therein; a pair of shutters (34, 36) slidably housed within opposed pockets (38, 40) (c. 4, ll. 40-48) formed at the upper part of the body so that a lower surface of each pocket is flush with the bottom surface of the recess (fig. 2), each of the shutters (34, 36) including through-holes (30, 32) respectively, each of the shutters (34, 36) including a horizontal portion (fig. 2) housed within the pocket (26) and a vertical portion (42, 44) formed in the end facing with respect to each other respectively, each of the through-holes (30, 32) of the shutters (34, 36) being provided at the vertical portion (42, 44); a longitudinally extending through-hole (12) disposed in the lower part of the body (c. 4, ll. 20-21), each of first and second artificial conduits (68, 70: fig. 7A) being

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fitted into respective ends of the longitudinally extending through-hole (12), the artificial conduits being disposed for anastomosis with a targeted artery or vein (fig. 9: c. 5, ll. 49-63); a pair of vertical through-holes (64, 66) communicating to the respective through holes of the shutters (30, 32) when they are opened (fig. 10; c. 6, ll. 1-3); and a cannula assembly connectable to a dialyzer (c. 5, ll. 41-42) including a pair of cannulas (68, 70), adapter (fig. 10: 62) for mounting cannula to body (c. 6, ll. 21-30) and locking member (63) for preventing the cannula from being removed (c. 5, ll. 58-59); whereby the device is arranged such that when each of the shutters is slid in a direction away from each other, the well is in communication with each of the artificial conduits through the longitudinally extending through-hole and the vertical through-holes of the body and each of the through-holes of the shutters (fig. 10), and when each of the shutters is slid in a direction near to each other, the well is out of communication with each of the artificial conduits (fig. 2) (c. 2, ll. 10-18), as recited in claim 1; and the peripheral wall passes through the skin (fig. 10) and the shutters are disposed at least partially (42, 44) outside the plane of the skin (fig. 10) as recited in claim 13.

4. With regard to claim 3, as best depicted in Figures 2 and 10, Kawamura discloses a recess (38, 40) which is used when the shutters (34, 36) are opened and closed (c. 4, ll. 40-45).

5. With regard to claims 7 and 8, as best depicted in Figures 3A, 3B, Kawamura discloses the locking member includes a projection (36a) for locking in a groove (34a) formed in a side surface of the vertical portion of each of the shutters (c. 4, ll. 60-61).

6. With regard to claims 10 and 11, as best depicted in Figures 3A, 3B, Kawamura discloses the locking member further comprises a groove (34 a) for being locked in a projection (36a) formed in a side surface of the vertical portion of the shutters.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

8. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

9. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,524,273 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because ‘273 claims the substantially identical subject matter except for the issued patent recites a rotating valve and the instant claims recite a sliding valve. The sliding shutters slide into open and closed positions to bring the well in and out of communication with the artificial conduits. The “columnar internal body” (40) recited in the issued claims is rotated into open and closed positions to perform the identical function as the instant shutters (figs. 2-10) in the manner of a stopcock valve which is rotated to open or close a conduit. Both structures perform valve functions of opening and closing the apertures except one is slid and the other is rotated. Valves

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are known from everyday life to perform the function of opening and closing, and the instant application merely substitutes one valve for another equivalent valve to perform the known function.

Response to Arguments

11. Applicant's arguments filed 8/23/2007 have been fully considered but they are not persuasive.

12. With respect to the prior art rejection under 35 USC 102(b), Applicant argues the following:

13. Kawamura does not teach "a pair of shutters... each of the shutters including through-holes" as recited in independent claims 1 and 13, therefore a *prima facie* case of anticipation under 35 USC 102(b) has not been made.

14. This argument is not persuasive for the following reason:

15. As detailed *supra*, and as best depicted in Figure 10, Kawamura teaches shutters (34, 36) including through-holes (30, 32).

16. The dictionary definition of "including" is defined as:

17. 1 : to shut up : ENCLOSE 2 : to take in or comprise as a part of a whole or group 3 : to contain between or within <two sides and the *included* angle>

18. As best depicted in Figure 10, when the shutters (34, 36) are slid open, the through-holes (30, 32) are contained within the vertical portions (42, 44) of the shutters and thus are included with the shutters. The claims as presently written do not require that the through-holes be formed through the material comprising the vertical portions of the shutters.

19. With respect to the obviousness-type double patenting, Applicant argues the following:

20. In order to justify a double patenting rejection, an analysis of the claims at issue is required, not an analysis limited to the disclosure of the patent.

21. This argument is not persuasive for the reasons detailed *supra* in the analysis of the patented '273 claims and the instant claims.

Conclusion

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/
Examiner, Art Unit 3761
3/13/08

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761